



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2012-0727; FRL-9376-7]

RIN 2070-AB27

Proposed Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 37 chemical substances which were the subject of premanufacture notices (PMNs). Seventeen of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action would require persons who intend to manufacture, import, or process any of these 37 chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2012-0727, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2012-0727. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2012-0727. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances in this proposed rule. The following list of North American Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a final SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a

proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
 - ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
 - iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
 - iv. Describe any assumptions and provide any technical information and/or data that you used.

- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

These proposed SNURs would, when finalized, require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of the specific chemical substances identified in the PMNs for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted

TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) and 40 CFR part 721 require persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700.

According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 37 chemical substances that are the subject of these proposed SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Proposed Rule

EPA is proposing to establish significant new use and recordkeeping requirements for 37 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).

- Basis for the TSCA section 5(e) consent order or, for TSCA non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this proposed rule.

This proposed rule includes 14 PMN substances whose reported chemical names include the term “carbon nanotube” or “carbon nanofibers.” Because of a lack of established nomenclature for carbon nanotubes, the TSCA Inventory names for carbon nanotubes are currently in generic form, e.g., carbon nanotube (CNT), multi-walled carbon nanotube (MWCNT), double-walled carbon nanotube (DWCNT), or single-walled carbon nanotube (SWCNT). EPA uses the specific structural characteristics provided by the PMN submitter to more specifically characterize the TSCA Inventory listing for an individual CNT. All submitters of new chemical notices for CNTs have claimed those specific structural characteristics as CBI. EPA is publishing the generic chemical name along with the PMN number to identify that a distinct chemical substance was the subject of the PMN without revealing the confidential chemical identity of the PMN substance. Confidentiality claims preclude a more detailed description of the identity of these CNTs. If an intended manufacturer, importer, or processor of CNTs is unsure of whether its CNTs are subject to this proposed SNUR or any other SNUR, the company can either contact EPA or obtain a written determination from EPA pursuant to the bona fide procedures at § 721.11. EPA is using the specific structural characteristics for all CNTs submitted as new chemical substances under TSCA to help develop standard nomenclature for placing these

chemical substances on the TSCA Inventory. EPA has compiled a generic list of those structural characteristics entitled “Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature.” A copy of this list is available in the docket for these proposed SNURs under docket ID number EPA–HQ–OPPT–2012–0727. If EPA develops a more specific generic chemical name for these materials, that name will be made publicly available.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including exceeding production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this proposed rule, may be claimed as CBI.

This proposed rule includes 17 PMN substances for which EPA determined, pursuant to TSCA section 5(e), that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal may present an unreasonable risk of injury to human health or the environment. Accordingly, these substances are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I). Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “section 5(e) SNURs” on these PMN substances are proposed pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The section 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) consent order usually requires, among other things, that potentially exposed employees

wear specified respirators unless actual measurements of the workplace air show that airborne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELS provisions in TSCA section 5(e) consent orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will normally state that persons subject to the SNUR who wish to pursue NCELS as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELS approach for SNURs are approved by EPA will be required to comply with NCELS provisions that are comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This proposed rule also includes SNURs on 20 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.” These so-called “non-section 5(e)

SNURs” are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a “significant new use” in all non-section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, “(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

PMN Number P-00-835

Chemical name: Substituted picolinate (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the substance will be used as an intermediate in the manufacture of agricultural chemicals. Based on ecological structure activity relationship (EcoSAR) analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 90 parts per billion (ppb) of the PMN substance in surface waters. As described in the PMN, releases to surface water are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 90 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10637.

PMN Number P-02-167

Chemical name: Lithium metal phosphate (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an electrode material. Based on EcoSAR analysis of test data on analogous inorganic phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases to water are not expected to exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance presents an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal

toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10638.

PMN Number P-02-668

Chemical name: Siloxanes and Silicones, di-Me, polymers with Ph silsesquioxanes, hydrolyzed, reaction products with 2-[[3-(trimethoxysilyl)propoxy]methyl]oxirane.

CAS number: 478823-10-8.

Basis for action: The PMN substance will be used as a binder for silicone coatings. Based on structure activity relationship (SAR) analysis of test data on analogous epoxides and alkoxysilanes, EPA identified concerns for mutagenicity, oncogenicity, reproductive toxicity, developmental toxicity, lung toxicity, and sensitization from dermal and inhalation exposures to the PMN substance. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of impervious gloves and a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that manufacturing, processing, and use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without impervious gloves where there is a potential for dermal exposure; any use of the substance without a NIOSH-certified respirator with an APF of at least 10; or any use of the substance in consumer products may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465), with attention to the pathology of the reproductive organs, and a carcinogenicity test (OPPTS Test Guideline 870.4200) would help to characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10639.

PMN Number P-03-135

Chemical name: 1,2-Cyclohexanedicarboxylic acid, 1-(2-ethylhexyl) 2-(2-methylpropyl) ester.

CAS number: 252958-29-5.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a compressor lubricant. Based on EcoSAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. There are two other chemical substances identified in the PMN that are already on the TSCA Inventory. The SNUR does not apply to those chemical substances. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS

Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help to characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10640.

PMN Number P-03-255

Chemical name: Phenol and vinyltoluene based hydrocarbon resin (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a diluent for coatings. Based on EcoSAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases to water are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help to characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10641.

PMN Numbers P-03-762 and P-03-763

Chemical name: Modified polyisocyanates (generic).

CAS number: Claimed as confidential.

Basis for action: The consolidated PMN states that the generic (non-confidential) use of the substances will be as hardeners. Based on SAR analysis of test data on analogous isocyanates, EPA has identified concerns for sensitization and irritation from dermal and inhalation exposure to the PMN substances. For the use described in the PMN, significant occupational inhalation and dermal exposures are not expected due to no domestic manufacture, use of impervious gloves, and no use of the substances involving an application method that generates a vapor, mist, or aerosol. Further, consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed processing or use of the substances may present an unreasonable risk. EPA has determined, however, that any domestic manufacture of the substances; any use of the substances without impervious gloves where there is a potential for dermal exposures; any use of the substance in consumer products; or any use of the substances involving an application method that generates a vapor, mist, or aerosol may result in serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substances.

CFR citation: 40 CFR 721.10642.

PMN Number P-04-640

Chemical name: Diisocyanate terminated polycarbodiimide (generic).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: February 1, 2006.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a crosslinking agent for solvent-based inks; a monomer for polymerization; and a water scavenger for producing anhydrous polymers. The PMN did not identify consumer uses for the PMN substance. Based on SAR analysis of test data on structurally similar diisocyanates, EPA identified concerns for dermal sensitization, respiratory sensitization, and pulmonary toxicity from exposure to the PMN substance by the inhalation and dermal routes. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health. To protect against these risks, the order requires:

1. Use of personal protective equipment including impervious gloves (when there is potential dermal exposure) and either a NIOSH-certified respirator with an APF of at least 2,000, or compliance with a NCEL of 0.05 mg/m^3 as an 8-hour time-weighted average (when there is potential inhalation exposure).

2. Establishment and use of a hazard communication program. The SNUR would designate as a “significant new use” the absence of these protective measures and consumer use of the PMN substance.

Recommended testing: EPA has determined that data from worker exposure to the PMN substance (such as inhalation monitoring data generated according to the NCELs section of the consent order) or a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance. The

order does not require submission of the testing at any specified time or production volume. However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10643.

PMN Number P-07-553

Chemical name: Reaction product of aluminum hydroxide and modified alkoxysilane (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the substance will be used as a flame retardant.

Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity from inhalation exposures to the PMN substance. At an annual production volume of 100,000 kilograms (kgs), significant occupational inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposure; or any increase of the annual 100,000 kg production volume may result in increased exposure to the PMN substance, which may cause serious human health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with a 60-day holding period would help characterize the health effects of the PMN substance.

CFR citation: 40 CFR 721.10644.

PMN Number P-08-392

Chemical name: Multi-walled carbon nanotube (generic) (P-08-392).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: November 14, 2008.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an antistatic, reinforcement additive. Based on test data on the PMN substance, and SAR analysis of test data on structurally similar respirable, poorly soluble particulates, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that the PMN substance may present an unreasonable risk of injury to human health. To protect against these risks, the order:

1. Requires use of personal protective equipment including impervious gloves and protective clothing (when there is a potential dermal exposure) and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an APF of at least 50 (when there is potential inhalation exposure).
2. Prohibits manufacture of the PMN substance in the United States.
3. Restricts processing and use of the PMN substance to those uses specified in the consent order.

The SNUR would designate as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 413) in rats with a post exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis and certain material characterization data, would help characterize possible effects of the substance. In the consent order, the PMN submitter has agreed to perform these tests within 18 months of commencing non-exempt commercial manufacture.

CFR citation: 40 CFR 721.10645.

PMN Number P-09-257

Chemical name: Multi-walled carbon nanotube (generic) (P-09-257).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: August 11, 2009.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) uses of the substance will be as an electric conductive filler to replace conventional material such as carbon black or carbon fiber in matrixes such as polymer resin for conductive applications, and an additive for elastomers, polymers, and resins to enhance mechanical properties. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and other CNTs, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. Further, available data suggests that pulmonary deposition of some nanoparticles, including CNTs, may induce cardiovascular toxicity if inhaled. Although there are no

environmental toxicity studies on CNTs available, EPA expects that some fraction of the CNTs, if released into the environment, will eventually be suspended in water. There have been sublethal effects observed for single walled CNTs in rainbow trout at levels as low as 100 ppb. The order was issued under section 5(e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the order:

1. Requires use of personal protective equipment including impervious gloves and protective clothing (when there is a potential dermal exposure) and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an APF of at least 50 (when there is potential inhalation exposure).
2. Prohibits manufacture of the PMN substance in the United States.
3. Restricts processing and use of the PMN substance to those uses specified in the consent order.
4. Prohibits release to water during processing and use.

The SNUR would designate as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post exposure observation period of up to 3 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart) and development of data on certain physical/chemical properties would help characterize possible effects of the substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume/time limit

(whichever comes first) without performing the 90-day test on the PMN substance. In addition, in the consent order, the PMN submitter agreed to provide the physical/chemical properties data within a specified time limit.

CFR citation: 40 CFR 721.10646.

PMN Numbers P-10-115, P-10-116, P-10-117, P-10-118, P-10-119, P-10-120, P-10-121, P-10-122, P-10-123, P-10-124, P-10-125, and P-10-126

Chemical name: Multi-walled carbon nanofibers (generic).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: May 9, 2011.

Basis for TSCA section 5(e) consent order: The PMNs state that the uses of the substances will be as electrical and thermal conductivity additives, mechanical reinforcement additives, energy storage additives, and chemical intermediates. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and other CNTs, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. Further, available data suggests that pulmonary deposition of some nanoparticles, including CNTs may induce cardiovascular toxicity if inhaled. Although there are no environmental toxicity studies on CNTs available, EPA expects that some fraction of the CNTs, if released into the environment, will eventually be suspended in water. There have been sub-lethal effects observed for single walled CNTs in rainbow trout at levels as low as 100 ppb. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that these substances may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the order:

1. Requires use of personal protective equipment including impervious gloves and protective clothing (when there is a potential dermal exposure) and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an APF of at least 50 (when there is potential inhalation exposure).
2. Restricts use of the PMN substances to use only as electrical and thermal conductivity additives, mechanical reinforcement additives, energy storage additives, and chemical intermediates as specified in the consent order.
3. Restricts processing and use of the PMN substances to industrial settings.
4. Prohibits release of the PMN substances into the waters of the United States during processing and use activities.

The SNUR would designate as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain physical/chemical properties data, workplace exposure monitoring and characterization testing, and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats would help characterize the human health effects of the PMN substances. The PMN submitter agreed to provide the physical/chemical properties data for the PMN substances within one year after submitting the notice of commencement. The consent order contains two additional production volume limits. The PMN submitter agreed not to exceed the first production volume limit without submitting workplace exposure monitoring and characterization testing (including byproducts) as well as quantification and characterization of substances that may be released during exposures typical during the use phase, such as handling, tearing and cutting the PMN substances. The PMN

submitter has also agreed not to exceed the second production volume limit without performing two 90-day inhalation toxicity tests, with a post-exposure observation period of up to 3 months, BALF analysis, aggregation/agglomeration state, shape, size/size particle distribution and surface properties of materials as administered, aggregation/agglomeration state, shape, size/size particle distribution and surface properties of materials of the delivered materials after administration, determination of cardiovascular toxicity, heart histopathology, and data on pulmonary deposition. One 90-day inhalation toxicity test will be conducted from a representative PMN substance in the group P-10-115, P-10-116, P-10-117, P-10-118, P-10-119, and the other 90-day inhalation toxicity test will be conducted from a representative PMN substance in the group P-10-120, P-10-121, P-10-122, P-10-123, P-10-124, P-10-125, and P-10-126.

CFR citation: 40 CFR 721.10647.

PMN Numbers P-10-545 and P-10-546

Chemical name: Modified lithium iron phosphates (generic).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: December 10, 2010.

Basis for TSCA section 5(e) consent order: The consolidated PMN states that the generic (non-confidential) use of the substances will be as battery electrode components, contained use. Based on test data on analogous respirable, poorly soluble particulates, there is potential risk for adverse lung effects including cancer, lung fibrosis, lung inflammation and systemic effects, including immunotoxicity. EPA has identified concerns for these health effects from exposures to the PMN substances. Based on EcoSAR analysis of test data on analogous phosphates, EPA predicts toxicity to aquatic

organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that these substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the consent order:

1. Restricts manufacturing, processing, and use of the substances to a fully-enclosed and automated process, including all loading and unloading activities.
2. Restricts use of the PMN substances to use only as specified in the consent order.
3. Prohibits release of the PMN substances into the waters of the United States during processing and use activities.

The SNUR would designate as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of up to 3 months, including BALF analysis; an algal toxicity test (OCSPP Test Guideline 850.5400); and physical/chemical properties testing for: Water solubility (OECD Test Guideline 105); surface chemistry, particle size distribution of the PMN substances, dustiness test (European Standard 15051); and particle size distribution, aggregation state, and porosity would help characterize the human health and environmental effects of the PMN substances. The PMN submitter has agreed not to exceed the confidential production volume in the consent order without performing the 90-day inhalation toxicity test and the physical/chemical properties tests.

CFR citation: 40 CFR 721.10648.

PMN Number P-11-115

Chemical name: MDI modified polyalkylene glycol adipate polyester (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10649.

PMN Number P-11-155

Chemical name: Polyether substituted anthraquinone derivative (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be used as a colorant for cleaners and detergents. Based on EcoSAR analysis of test data on analogous aromatic amines and nonionic dyes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 1 ppb for more than 20 days per year.

Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as a colorant for cleaners and detergents may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075) and an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10650.

PMN Number P-11-290

Chemical name: Carbide derived nanocarbon (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a sensor element in an electrochemical sensor. Based on SAR analysis of test data on respirable, poorly soluble particulates, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity if the substances were manufactured by a method other than described in the PMN. Further, available data suggests that pulmonary deposition of some carbon-based nanoparticles, may induce cardiovascular toxicity if inhaled. EPA identified concerns for lung toxicity to workers from inhalation exposures to the PMN substance. For the manufacture method described in the PMN, significant dermal and inhalation exposures are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that manufacture of the substance by a method other than as described in the PMN may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that inhalation monitoring data collected during the manufacturing process according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in the docket under docket ID number EPA-HQ-OPPT-2012-0727) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10651.

PMN Numbers P-11-309, P-11-311, P-11-312, P-11-313, and P-11-314

Chemical names: (P-11-309) Hexanedioic acid, polymer with polyether polyol, 1,1'-methylenebis[4-isocyanatobenzene] and dihydroxydialkyl ether (generic); (P-11-311) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic); (P-11-312) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic); (P-11-313) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether, reaction products with dialkylcarbinol (generic); and (P-11-314) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether reaction products with dialkylcarbinol (generic).

CAS numbers: Claimed as confidential.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as industrial adhesives. Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances. For the use described in the PMNs, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has

determined, however, that any use of the substances without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substances in consumer products may cause serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substances.

CFR citations: 40 CFR 721.10652 (P-11-309); 40 CFR 721.10653 (P-11-311); 40 CFR 721.10654 (P-11-312); 40 CFR 721.10655 (P-11-313); and 40 CFR 721.10656 (P-11-314).

PMN Number P-12-73

Chemical name: Castor oil, polymer with hydrogenated vegetable oil, 1,1'-methylenebis[isocyanatobenzene] and isocyanate (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an industrial adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for sensitization. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use

of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substances in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) in rodents would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10657.

PMN Number P-12-133

Chemical name: 2-Oxepanone, polymer with 1,6-diisocyanatohexane, 2,2"-dimethyl-1,3-propanediol and 2,2'-oxybis[ethanol].

CAS number: 1313708-90-5.

Basis for action: The PMN states that the substance will be used as a coating for wind craft wings. Based on SAR analysis of test data on structurally similar chemicals submitted under TSCA section 8(e), EPA identified concerns for oncogenicity and mutagenicity. Additionally, based on the isocyanate moiety, the Agency identified concerns for sensitization. For the use described in the PMN, significant occupational inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified

respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity study (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10658.

PMN Number P-12-143

Chemical name: Poly(oxy-1,4-butanediyl), -hydro--hydroxy-, polymer with alkyldiisocyanates (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a crosslinking resin. Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and respiratory exposures to the PMN substance. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substance in consumer products may

cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10659.

PMN Number P-12-274

Chemical name: Aliphatic diisocyanate adduct with substituted amino alkyl silane (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an adhesive. Based on SAR analysis of test data on analogous isocyanates, EPA identified concern for sensitization from dermal and inhalation exposure to the PMN substance. Additionally, liquid and vapor contact with the eye can cause moderate to severe irritation. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures;

or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10660.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for 17 of the 37 chemical substances regulation was warranted under TSCA section 5(e) pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The proposed SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are being proposed pursuant to § 721.160.

In the other 20 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA would be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA would ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Notice and Comment Procedures

EPA is issuing these SNURs by notice and comment procedure, as described in § 721.170(d)(4). In accordance with § 721.170(d)(4)(ii)(A), persons are being given the opportunity to submit comments on or before *[insert date 60 days after date of publication in the **Federal Register**]* on whether EPA should establish notification requirements.

VII. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant “new” use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 17 chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. EPA is soliciting comments on whether any of the uses proposed as significant new uses are ongoing.

As discussed in the **Federal Register** of April 24, 1990 SNUR, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the rule became final, and then argue that the use was ongoing before the effective date of the final rule. Thus, persons who begin commercial manufacture, import,

or processing of the chemical substances that would be regulated through these proposed SNURs will have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including any extensions, expires.

EPA has promulgated provisions to allow persons to comply with these proposed SNURs before the effective date. If a person meets the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests

are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or Source OECD at <http://www.sourceoecd.org>. To access the European Standard, EN 15051 method, issued by The European Committee for Standardization (CEN), please go to <http://www.cen.eu/cen/products>.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this proposed rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

When physical/chemical properties of test material and/or material characterization tests are recommended for nanoscale substances that are the subject of

this proposed rule, you should take into consideration the characterizations identified in the Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme, which is available at [http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2009\)20/rev&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)20/rev&doclanguage=en).

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-

PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at

<http://www.epa.gov/opptintr/newchems>.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2012-0727.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs, and, in some cases, TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "*Regulatory Planning and Review*" (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA would amend the table in 40 CFR part 9 to list the OMB approval number for the information

collection requirements contained in this proposed rule, if the SNUR is subsequently issued as a final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of these SNURS would not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this proposed rule.

This proposed rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit X. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be

impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 15, 2013.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.10637 to subpart E to read as follows:

§ 721.10637 Substituted picolinate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted picolinate (PMN P-00-835) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=90).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

3. Add § 721.10638 to subpart E to read as follows:

§ 721.10638 Lithium metal phosphate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as lithium metal phosphate (PMN P-02-167) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

4. Add § 721.10639 to subpart E to read as follows:

§ 721.10639 Siloxanes and Silicones, di-Me, polymers with Ph silsesquioxanes, hydrolyzed, reaction products with 2-[[3-(trimethoxysilyl)propoxy]methyl]oxirane.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as siloxanes and silicones, di-Me, polymers with Ph silsesquioxanes, hydrolyzed, reaction products with 2-[[3-(trimethoxysilyl)propoxy]methyl]oxirane (PMN P-02-668; CAS No. 478823-10-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

5. Add § 721.10640 to subpart E to read as follows:

§ 721.10640 11,2-Cyclohexanedicarboxylic acid, 1-(2-ethylhexyl) 2-(2-methylpropyl) ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,2-cyclohexanedicarboxylic acid, 1-(2-ethylhexyl) 2-(2-methylpropyl) ester (PMN P-03-135; CAS Nos. 252958-29-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

6. Add § 721.10641 to subpart E to read as follows:

§ 721.10641 Phenol and vinyltoluene based hydrocarbon resin (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenol and vinyltoluene based hydrocarbon resin (PMN P-03-255) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

7. Add § 721.10642 to subpart E to read as follows:

§ 721.10642 Modified polyisocyanates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as modified polyisocyanates (PMNs P-03-762

and P-03-763) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (b) (concentration set at 0.1 percent), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (o), and (y)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

8. Add § 721.10643 to subpart E to read as follows:

§ 721.10643 Diisocyanate terminated polycarbodiimide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as diisocyanate terminated polycarbodiimide (PMN P-04-640) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(3), (a)(4), and (a)(6)(ii). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece with an assigned protection factor (APF) of at least 2,000 meets the minimum requirements § 721.63(a)(4). As an alternative to the respiratory requirements listed here, a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.05 mg/m^3 . Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (f), (g)(1)(i), (g)(1)(ii), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv) (use respiratory protection or maintain airborne concentrations at or below an 8-hour time-weighted average of 0.05 mg/m^3), (g)(2)(v), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

9. Add § 721.10644 to subpart E to read as follows:

§ 721.10644 Reaction product of aluminum hydroxide and modified alkoxysilane (generic).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as reaction product of aluminum hydroxide and modified alkoxysilane (PMN P-07-553) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (b) (concentrations set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(s) (100,000 kilograms).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

10. Add § 721.10645 to subpart E to read as follows:

§ 721.10645 Multi-walled carbon nanotube (generic) (P-08-392).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotube (PMN P-08-392) is subject to reporting under this section for the significant new uses described in

paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured); incorporated or embedded into a polymer matrix that itself has been completely reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in §721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (a)(6) (particulate, including solids or liquid droplets). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an assigned protection factor (APF) of at least 50 meet the minimum requirements of § 721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k), and (q) (within 18 months of commencing non-exempt commercial manufacture).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

11. Add § 721.10646 to subpart E to read as follows:

§ 721.10646 Multi-walled carbon nanotube (generic) (P-09-257).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotube (PMN P-09-257) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured); incorporated or embedded into a polymer matrix that itself has been completely reacted (cured); embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing; or incorporated into an article as defined at 40 CFR 720.3(c).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (a)(6) (particulate, including solids or liquid droplets). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control

measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an assigned protection factor (APF) of at least 50 meets the minimum requirements of § 721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k), and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

12. Add § 721.10647 to subpart E to read as follows:

§ 721.10647 Multi-walled carbon nanofibers (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanofibers (PMNs P-10-115, P-10-116, P-10-117, P-10-118, P-10-119, P-10-120, P-10-121, P-10-122, P-10-123, P-10-124, P-10-125, and P-10-126) are subject to reporting under this section for the

significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); incorporated or embedded into a polymer matrix that itself has been reacted (cured); embedded into a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing; or incorporated into an article as defined at 40 CFR 720.3(c).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (a)(6)(i). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an assigned protection factor (APF) of at least 50 meets the minimum requirements of § 721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) (electrical and thermal conductivity additive in encapsulated thermoplastics, thermosets, elastomers, glass, metals, and ceramics; mechanical reinforcement additive in encapsulated thermoplastics, thermosets, elastomers, glass, metals, and ceramics; energy storage additive; or chemical intermediate), (l) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

13. Add § 721.10648 to subpart E to read as follows:

§ 721.10648 Modified lithium iron phosphates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as modified lithium iron phosphates (PMNs P-10-545 and P-10-546) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured), embedded or incorporated into a polymer matrix that has been reacted (cured), or embedded in a permanent solid polymer form that is not intended to undergo further processing, except mechanical.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (a), (b), (c), (k), and (q).

(ii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (i), and (k) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

14. Add § 721.10649 to subpart E to read as follows:

§ 721.10649 MDI modified polyalkylene glycol adipate polyester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as MDI modified polyalkylene glycol adipate polyester (PMN P-11-115) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and

Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

15. Add § 721.10650 to subpart E to read as follows:

§ 721.10650 Polyether substituted anthraquinone derivative (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyether substituted anthraquinone derivative (PMN P-11-155) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (colorant for cleaners and detergents).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

16. Add § 721.10651 to subpart E to read as follows:

§ 721.10651 Carbide derived nanocarbon (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbide derived nanocarbon (PMN P-11-290) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (manufacture of the substance by the method described in the premanufacture notice).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

17. Add § 721.10652 to subpart E to read as follows:

§ 721.10652 Hexanedioic acid, polymer with polyether polyol, 1,1'-methylenebis[4-isocyanatobenzene] and dihydroxydialkyl ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with polyether polyol, 1,1'-methylenebis[4-isocyanatobenzene] and dihydroxydialkyl ether (PMN P-11-309) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

18. Add § 721.10653 to subpart E to read as follows:

§ 721.10653 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (PMN P-11-311) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g.,

workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

19. Add § 721.10654 to subpart E to read as follows:

§ 721.10654 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (PMN P-11-312) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

20. Add § 721.10655 to subpart E to read as follows:

§ 721.10655 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether, reaction products with dialkylcarbinol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether, reaction products with dialkylcarbinol (PMN P-11-313) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

21. Add § 721.10656 to subpart E to read as follows:

§ 721.10656 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenabis[4-isocyanatobenzene], dihydroxydialkyl ether reaction products with dialkylcarbinol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenabis[4-

isocyanatobenzene], dihydroxydialkyl ether reaction products with dialkylcarbinol (PMN P-11-314) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

22. Add § 721.10657 to subpart E to read as follows:

§ 721.10657 Castor oil, polymer with hydrogenated vegetable oil, 1,1'-methylenebis[isocyanatobenzene] and isocyanate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as castor oil, polymer with hydrogenated vegetable oil, 1,1'-methylenebis[isocyanatobenzene] and isocyanate (PMN P-12-73) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

23. Add § 721.10658 to subpart E to read as follows:

§ 721.10658 2-Oxepanone, polymer with 1,6-diisocyanatohexane, 2,2-dimethyl-1,3-propanediol and 2,2'-oxybis[ethanol].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-oxepanone, polymer with 1,6-diisocyanatohexane, 2,2-dimethyl-1,3-propanediol and 2,2'-oxybis[ethanol] (PMN P-12-133; CAS No. 1313708-90-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and

Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

24. Add § 721.10659 to subpart E to read as follows:

§ 721.10659 Poly(oxy-1,4-butanediyl), -hydro--hydroxy-, polymer with alkyldiisocyanates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as poly(oxy-1,4-butanediyl), -hydro--hydroxy-, polymer with alkyldiisocyanates (PMN P-12-143) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

25. Add § 721.10660 to subpart E to read as follows:

§ 721.10660 Aliphatic diisocyanate adduct with substituted amino alkyl silane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aliphatic diisocyanate adduct with substituted amino alkyl silane (PMN P-12-274) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in

§ 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

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